

Article for AMC-NOMA, Northern Ohio Physician

Title: CMS Updates the Stark Physician Self Referral Rule

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The Center for Medicare and Medicaid Services (CMS) revised the Stark II physician self-referral rule twice this year -- once with the Inpatient Hospital Final Rule and more recently with the Medicare Physician Fee Schedule (PFS) Rule. While some joint ventures and leasing arrangements will no longer be allowed, CMS has also provided some leeway with alternative methods of compliance when providers need a reprieve from the harsh demands of the rule.

The Stark law prohibits physician referrals to an entity for certain "designated health services" covered by Medicare if a financial relationship exists between the referring physician (or an immediate family member) and the entity, unless the arrangement meets an exception. An entity furnishing services pursuant to a prohibited referral may not bill Medicare for the services and, along with the physician, may be subject to civil monetary penalties and exclusion. Many of the changes under way will affect indirect relationships with hospitals, either through affiliated entities, joint ventures or physician organizations.

#### *October 2008 Changes to Compensation Relationships*

Under the "stand-in-the-shoes" requirement adopted last year, CMS presumes a financial relationship with each of the referring physicians in a physician organization when an entity that bills Medicare enters a financial relationship with the physician organization itself. CMS delayed application of the rule to academic medical centers and certain 501(c)(3) integrated healthcare system arrangements due to industry concerns that it would unnecessarily stifle the use of support payments from hospitals to affiliated physician practices.

Effective October 1, 2008, CMS narrowed the stand-in-the-shoes rule to those organizations with physician owners having profit distributions and investment returns. CMS specifically excluded physicians with only a titular interest (e.g., holding shares in trust for the benefit of a hospital) and physicians covered by the current academic medical center exception.

If a physician is eligible for profits and distributions as an owner in a physician organization having a financial relationship with an entity that bills Medicare for designated health services, the Stark law will now regulate that relationship directly and require a specific exception. As a result, most of these financial relationships will require a written agreement of at least one year that is commercially reasonable, signed by both parties in advance, and including payment terms consistent with fair market value for rent or any items and services provided.

In a brief respite, CMS created a grace period for arrangements that otherwise meet an exception but are missing the signatures required by the applicable exception. If the written agreement is missing the necessary signature, it can be obtained within 90 days if inadvertent (and within 30 days if non-inadvertent) so long as the other conditions are met and this alternative method has not been used within a three-year period.

Hospitals are also preparing for CMS to implement new Disclosure of Financial Relationship Reports (DFFR), requiring the hospital to furnish information to CMS within 60 days on all ownership and compensation arrangements with physicians. As a result of these changes, physicians and physician organizations can expect increased emphasis on both the disclosure of these relationships as well as the documentation required to pass muster and more rigid formalities when contracting with hospitals and health systems.

#### *October 2009 Changes to Joint Ventures and Leases*

CMS finalized to expand the types of entities regulated by the Stark law beyond simply those entities that bill Medicare directly and to tighten up the compensation methodologies that can be used in leases and certain compensation arrangements. Anticipating that the industry would need time to implement these structural changes, CMS allowed a grace period for transitioning to the new rule and it will not take effect until next October.

As expected, CMS finalized restrictions on “per click” and percentage-based leases governed by the Stark rule based on the concern that physicians will be rewarded for referrals (i.e., the rental charges reflect services provided to patients referred by the lessor physician to the hospital lessee based on a per-use or per-service fee). Rental payments for office space and equipment cannot be based on a percent of revenue or the number of procedures performed even if the payment is considered to be at fair market value. Office and equipment leases that are not based on a set, fixed-in-advance rental payment should be reviewed before the October 1, 2009 deadline and may need to be restructured if the leasing arrangement violates the new conditions.

In an about face, CMS reversed its previous position allowing “under arrangements” alignment models with hospitals. An “under arrangements” alignment model is a structure through which referring physicians provide goods and services to a hospital directly, or through a joint venture with the hospital, and the hospital then bills Medicare “under arrangements” and pays the joint venture for the services provided (e.g., imaging, outpatient services, cardiac cath labs). CMS considers turnkey arrangements whereby the joint venture performs essentially all of the services relating to the hospital service a business model fraught with problems and will begin to regulate the joint venture entity under Stark effective October 1, 2009. Outside the wholesale turnkey approach, hospitals can continue to obtain personnel and services from physician groups under the personal services exception and can lease space and equipment by avoiding per-click and percentage based rentals as set forth above, but the fine lines between the two business models must be analyzed on a case-by-case basis.

#### *On the Horizon: Gainsharing 2.0*

In the PFS Rule published in November, CMS re-opened for comment its proposal for certain arrangements allowing referring physicians to participate in hospital compensation pools for quality and cost savings initiatives. The AMA and others have previously commented that these so called “gainsharing” arrangements encourage collaboration, create hospital efficiencies, and fund quality initiatives if appropriately structured. Gainsharing is allowed currently if it meets the existing Stark exceptions, although these are considered a bit cumbersome.

Some observers are disappointed that CMS did not finalize a more flexible exception now. Instead, CMS solicited additional comments on 55 specific issues it is studying dealing with hospital shared savings and incentive payment programs for quality initiatives. CMS seems committed to working toward a solution that allows physicians to benefit from working more closely with hospitals while addressing concerns that sham measures and rewards for referrals would be allowed. Given that the U.S. Health and Human Services (HHS) Office of Inspector General (OIG) has now issued 12 advisory opinions approving gainsharing agreements, additional flexibility on the part of CMS for hospital and physician alignment on cost savings and quality improvement measures seems warranted. With value based purchasing and other Medicare reforms on the horizon, physicians and hospitals should delineate what CMS and the OIG consider to be proper in structuring both short- and long-term alignment strategies.

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